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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,401	03/25/2005	Joanne J. Fillatti	16518.145	7282

28381 7590 02/05/2008

ARNOLD & PORTER LLP  
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WASHINGTON, DC 20004-1206

EXAMINER
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MCELWAIN, ELIZABETH F

ART UNIT	PAPER NUMBER
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1638

MAIL DATE	DELIVERY MODE
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02/05/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/508,401	<b>Applicant(s)</b> FILLATTI ET AL.	
	<b>Examiner</b> Elizabeth F. McElwain	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 November 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) 7,8,13-21 and 27-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,9-12,22,23,25 and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____  |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :4/27/05;5/17/05;10/12/05;10/25/05;11/22/05;2/8/07;3/28/07.

### **DETAILED ACTION**

The amendment filed November 14, 2007 has been entered.

#### ***Election/Restrictions***

1. Applicant's election without traverse of Group I, claims 1-6, 9-12, 22, 23, 25 and 26, and species B drawn to suppression of expression of FAD2 and increase in expression of beta-ketoacyl-ACP synthase IV in the reply filed on November 14, 2007 is acknowledged. It is noted that applicants have chosen to withdrawn claims 39-72 drawn to nucleic acids. The Examiner will consider claims 39-72 as drawn to different inventions from the elected claims, therefore claims 39-72 will not be examined in the present application.

#### ***Claim Objections***

The claims are objected to for reciting non-elected species.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-6, 9-12, 22, 23, 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims

are drawn to a soybean seed having specified ranges of oleic acid, linoleic acid, linolenic acid and saturated fatty acids by weight. Claims are also drawn to said seeds produced by a seed comprising a first set of DNA sequences for suppression of at least FAD2 and FAD3 or FATB; and a second set of DNA sequences for increasing expression of at least a beta-ketacyl-ACP synthase IV gene. However, the specification does not disclose any soybean seeds having the claimed ranges of fatty acids prepared by any method.

De Luca teaches that modifying plant biosynthetic pathways by transforming plants with genes encoding enzymes involved in said pathway is highly unpredictable (see the paragraph bridging the columns on page 225N, for example), and that “on many occasions desired goals have been impossible to achieve” (see the last paragraph on page 228N).

Voelker et al (Annual Review of Plant Physiology and Plant Molecular Biology 52: 335-361, 2001) teach the complexity of plant lipid biosynthesis and the uncertainty of the resultant seed fatty acid composition when transforming plant species with heterologous genes (see page 345, the third full paragraph, for example). Voelker et al teach that there are “many hundreds of different fatty acids found in natural plant oils that are mostly produced as a result of changes in a few amino acids of a handful of lipid biosynthetic genes” (see page 354, the last paragraph) and that plants transformed with fatty acid biosynthesis genes from heterologous plant species do not always have fatty acid profiles that correspond to those of the plant from which the gene was cloned (see page 341, the first full paragraph). For example, soybean embryos transformed with a borage *delat-6* desaturase produce gamma-linolenic acid, but transformed canola seeds do not.

Voelker et al also teach that some plants have enzymes with specialized activities (page 344, the first full paragraph). However, the availability of enzyme substrates also has an effect

on the resultant fatty acid profile of a given plant species (see page 343, the third to last full sentence). In addition, Voelker et al teach the high degree of sequence similarity between fatty acid desaturases, wherein as few as two amino acids can result in a change in substrate specificity and as few as five amino acids can produce changes in both substrate and region-specificities of an acyl-ACP desaturase (see page 345, the first full paragraph). Furthermore, Voelker et al teaches that the hydroxylase enzyme from *Lesquerella* is bifunctional in that it has some omega-6 desaturase activity in addition to hydroxylase activity and that small differences in active site geometry are responsible for the different functional activities (see page 347, the last full paragraph). There are also FAD2 related sequences that function as epoxigenases and acetylenases (see pages 347-348, the paragraph bridging the pages).

Voelker et al also teach uncertainty with regard to the distribution of membrane and storage lipids in plants transformed with heterologous fatty acid biosynthesis genes (see the third full paragraph of page 351 and page 352, the second full paragraph). There are also reports of altered plant morphology and organelle structure in transgenic plants having modified fatty acid biosynthesis (page 353, the second full paragraph).

The modification of plant lipid composition to produce seeds having specified ranges of fatty acids by any method including transforming a plant with two nucleic acids for suppression of two genes and one nucleic acid for increased expression of a third gene is highly unpredictable. Given the high level of unpredictability of modifying plant fatty acid composition by transforming plants with fatty acid biosynthetic genes, as taught by DeLuca and Voelker et al; given the lack of working examples of soybean seeds transformed with any of the disclosed and claimed constructs, and the lack of working examples of soybean seeds having the claimed high

level of oleic acid and saturated fatty acids of 3 to 6% by weight; given the breadth of the claims which encompass soybean seeds having a multitude of fatty acid ranges and encompass soybean seeds transformed with an unlimited number of possible gene constructs comprising any FAD2 sequences of any number and any beta-ketoacyl-ACP synthase I gene in combination with a multitude of other sequences to produce the claimed fatty acid ranges in a soybean seed; and given the absence of guidance with regard to choosing from this multitude of constructs to produce and select for the claimed soybean seeds; it would require undue experimentation by one skilled in the art to make and use the invention.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Fehr et al (US Patent 5,714,670).

a. The claims are drawn to a soybean seed having an oil composition of 55 to 80% by weight oleic acid, 10 to 40% by weight linoleic acid, 6% or less by weight linolenic acid and 2 to 8% by weight saturated fatty acids, and a container of seeds wherein the container comprises at least 25% of seeds having said oil composition.

b. Fehr et al teach a soybean seed having 71.2% oleic acid, 15.9% linoleic acid, 2.1% linolenic acid, 7.7% palmitic acid and 3.2% stearic acid, wherein each of the saturated fatty acids (palmitic acid and stearic acid) is between 2% and 8% by weight. Fehr et al teach a deposit of said seed, wherein said deposit would represent 2500 seeds in a container that comprise at least 25% seeds having said fatty acid composition, wherein all of the seeds would have the claimed fatty acid composition.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Application/Control Number:  
10/508,401  
Art Unit: 1638

Page 7

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Elizabeth F. McElwain  
Primary Examiner  
Art Unit 1638

EFM